GUIDELINES FOR REQUESTING CERTIFICATES OF FREE SALE

During the past few years requests by the food, drug, and cosmetic industries for Certificates of Free Sale, in order to ship products to foreign countries, have increased dramatically. The volume has, on occasions, created delays in the issuance of certificate requests. In an effort to expedite the processing of these requests, your firm will be responsible for typing the pertinent information on state forms which will be supplied by this Department. The <u>TYPED</u> certificates should be forwarded to the Department along with the support documentations as indicated below. Attached is an example showing how these forms should be prepared. A limit of 25 products must be typed on the Certificates of Free Sale form.

A basic requirement for obtaining a Certificate of Free Sale is a current Satisfactory inspection rating of your food or cosmetic establishment on file with the Department. In the case of a drug manufacturer, the applicant should include the last Good Manufacturing Practice (GMP) inspection by the U.S. Food and Drug Administration which will be verified prior to issuance of a certificate. In addition to the inspection record, we require labels of the product(s) you are exporting. Original labels only and all labeling material should be submitted along with your request (facsimiles, copies, or label proofs are not acceptable).

In order that we can process your request for certificates as promptly as possible, it is essential that the labels submitted be in compliance with the laws and regulations enforced by this Department and the U. S. Food and Drug Administration.

If the country to which your products are going requires certification of our notary public=s signature, a check or money order for \$25 for each separate certificate will be submitted to the Division of Revenue, Commercial Recording. The check is made payable to the State Treasurer and should be sent with your request. The Treasury Department, not the DHSS, will expedite your request by remitting \$40 instead of the \$25 fee. The DHSS would still have to review your labels for 10 business days.

An alternative to using the Division of Revenue, Commercial Recording office, is to use the Mercer County Clerk=s office for notary certification. The Mercer County Clerk=s office is presently charging \$5 for each separate certificate. The check is made payable to the Mercer County Clerk.

We will forward your certificates to either of the above offices provided checks or money orders accompany your request. You may include a self-addressed and stamped envelope to expedite your request to the Mercer County Clerks office or to the Department of Treasury.

This office does not charge a fee for issuing certificates. The fee is in conjunction with the notary public=s signature certification only and not all countries require this additional certification.

Requests for Certificates of Free Sale should only be made for the actual export shipment involved. Advance certifications should not be requested. Also, please enclose a cover letter with all Certificates of Free Sale indicating a contact person along with their telephone number and a self addressed stamped envelope or prepaid airbill for overnight delivery. Normal processing time is ten working days from the date of receipt.

We hope that the information will help to clarify the requirements for obtaining certificates and expedite your requests. If you are in need of additional information, please do not hesitate to call the Food and Drug Safety Program at (609) 588-3123. Additional forms may be obtained by contacting Jane Steinouer, Secretarial Assistant, at (609) 588-7483.

revised: 8/8/04